DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-2021-21DZ; Docket No. CDC-2021-0031]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies. The aim of the project is to create harm reduction products that can help: 1) facilitate greater access to sterile syringes through pharmacy-based non-prescription syringe sales (NPSS), 2) minimize the burden of NPSS distribution on pharmacists, and 3) improve pharmacy personnel's understanding of, and skills with, NPSS efforts.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2021-0031 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.
5. Assess information collection costs.

Proposed Project

Harm Reduction Toolkit for Non-Prescription Syringe Sales in Community Pharmacies – New - National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Injection drug use, through shared use of injection equipment, increases risk of acquiring blood borne pathogens such as HIV and hepatitis C virus (HCV). While stopping injection drug use is an optimal goal for preventing transmission of bloodborne pathogens among persons who inject drugs (PWID), it is not always achievable. However, use of sterile needles and syringes, for each injection, can significantly reduce risk of acquiring bloodborne pathogens and access to sterile syringes can reduce needle sharing among PWID.

Community pharmacies are in a unique position to provide access to sterile syringes through non-prescription syringe sales (NPSS). Pharmacies are in this position partly because they are among the most accessible of healthcare settings. In fact, approximately 90% of urban costumers live within two miles of a pharmacy and 70% of rural costumers are within 15 miles of a pharmacy. Pharmacies also have extended hours of operations making them more accessible to patients. While pharmacies represent potential sites for NPSS, education and tools are

needed to build pharmacists' NPSS-related skills and to support pharmacists in the delivery of NPSS and other harm reduction services.

The overarching aim of this project is to create harm reduction products that can help: 1) facilitate greater access to sterile syringes through pharmacy-based NPSS 2) minimize the burden of NPSS distribution on pharmacists, and 3) improve pharmacy personnel's understanding of, and skills with, NPSS efforts. The project will demonstrate how pharmacy personnel can use a contractor developed harm reduction kit for PWID and online training videos for pharmacy personnel on NPSS, for HIV prevention.

CDC requests OMB approval to collect standardized data from an in-field demonstration and evaluation of three contractor developed resources for harm reduction: harm reduction kit for persons who inject drugs (PWID); online training videos for pharmacists and pharmacy personnel regarding NPSS; and a resource website for PWID. The in-field demonstration and evaluation will take place at 12 project pharmacies over one six-week period. The information collection has three primary components: 1) online pre-test and post-test surveys 2) number of pharmacy syringe sales and service referrals, and 3) website usage (for the training website and the resource website for PWID). Pharmacy personnel who participate in the in-field demonstration will complete a one-time online pre-test survey and a one-time online post-test survey. The pre-test survey will

be completed in the week prior to the participants being given access to the online training videos for pharmacists and pharmacy personnel regarding NPSS and the post-test survey will be completed in the week following the one-week training period. An estimated 60 pharmacy personnel will complete the pre-test and post-test surveys. Data from the pre/post-test surveys will be collected entirely online. The purpose of the surveys is to assess pharmacy personnel's skills and knowledge pertaining to NPSS before and after access to the NPSS online training. Data on pharmacy syringe sales and service referrals (e.g., referrals for HIV testing and substance use treatment) will be collected from each of the 12 participant pharmacies store or log records before and after the one-week training period. Each participant pharmacy's manager will conduct a one-time data collection of aggregated syringe sales and service referrals data from the 30-day period before and after the training period. The purpose of these data is to describe syringe sales and service referrals before and after pharmacy personnel's access to the NPSS online training. Lastly, one project director will determine website usage of the training website and resource locator for PWID. Training website usage data will be paired with the pre-test and post-test surveys and skill scores and analyzed for correlations between usage and knowledge, comfort, and use of NPSS skills. The numbers of syringe customers and service referrals and usage of the resource website for PWID will be described.

CDC requests OMB approval for an estimated 73 annual burden hours. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Pharmacists and pharmacy technicians	Pre-test survey	60	1	30/60	30
Pharmacists and pharmacy technicians	Post-test survey	60	1	30/60	30
Pharmacy manager	Pharmacy syringe sales and service referrals	12	1	60/60	12
Project director	Website usage	1	1	15/60	1
Total					73

Jeffrey M. Zirger,

Lead,

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Office of Scientific Integrity,

Office of Science,

Centers for Disease Control and Prevention.

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